Claims

1. A stent comprising,

first and second terminal ends spaced apart from each other, and

a wall, disposed between the first and second terminal ends, and including an inner surface and an outer surface, the inner surface defining a lumen extending between the first and second ends, and the outer surface having a substantially smooth portion, the wall having,

a first outside cross-sectional diameter at the first terminal end, a second outside cross-sectional diameter at the second terminal end, and at least one intermediate outside cross-sectional diameter at an intermediate location between the first and second terminal ends, wherein at least one of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter, and

an expanded state and a collapsed state, the wall being adapted to spontaneously revert from the collapsed state to the expanded state.

2. A stent according to claim 1 wherein the first terminal end of the stent is adapted for residing at a bladder end of a prostatic urethra of a patient and the second terminal end of the stent is adapted for residing at an external sphincter end of the prostatic urethra.

3. A stent according to claim 1 wherein the substantially smooth portion of the outer surface of the wall is adapted to inhibit tissue-in-growth.

4. A stent according to claim 1, wherein at least one of the first and second terminal ends include a retention ring, having an expanded ring state and a collapsed ring state and being adapted to spontaneously revert from the collapsed ring state to the expanded ring state, and in the expanded ring state, the retention ring extending axially from the wall of the stent.

5. A stent according to claim 4 wherein the retention ring includes an annular elastic core.

6. A stent according to claim 5 wherein the annular elastic core includes a nickel-titanium alloy.

7. A stent according to claim 1 wherein the first terminal end includes a retention ring, having an expanded ring state and a collapsed ring state, and being adapted to spontaneously revert from the collapsed ring state to the expanded ring state to facilitate retention of the retention ring within the bladder of the patient, and in the expanded ring state, the retention ring extending axially from the wall of the stent.

8. A stent according to claim 1 wherein the second terminal includes a retention ring, having an expanded ring state and a collapsed ring state, and being adapted to spontaneously revert from the collapsed ring state to the expanded ring state to inhibit the retention ring from passing through an external sphincter of the prostatic urethra of the patient, and in the expanded ring state, the retention ring extending axially from the wall of the stent.

9. A stent according to claim 1 wherein

the first terminal end includes a first retention ring, having a first expanded ring state and a first collapsed ring state, in the first expanded ring state, the first retention ring extending axially from the wall of the stent, and being adapted to spontaneously revert from the first collapsed ring state to the first expanded ring state to facilitate retention of the first retention ring within the bladder of the patient, and

the second terminal end includes a second retention ring, having a second expanded second ring state and a second collapsed ring state, in the second expanded ring state, the second retention ring extending axially from the wall of the stent, and being adapted to spontaneously revert from the second collapsed ring state to the second expanded ring state to inhibit the second retention ring from passing through the external sphincter of the prostatic urethra of the patient.

10. A stent according to claim 1 wherein the wall further comprises at least one through aperture extending between the inner surface and the outer surface for providing fluid communication between the inner surface and the outer surface.

11. A stent according to claim 1 wherein the first outside cross-sectional diameter is greater than the second outside cross-sectional diameter.

12. A stent according to claim 1 wherein the second outside cross-sectional diameter is greater than the first outside cross-sectional diameter.

13. A stent according to claim 1, wherein the first terminal end comprises a domed segment having inner and outer surfaces and extending axially from the wall of the stent and adapted for facilitating insertion of the stent into the patient.

14. A stent according to claim 13 wherein the domed segment further comprises at least one through aperture extending radially between the inner and outer surfaces of the domed segment to provide fluid communication between the inner and outer surfaces of the domed segment.

15. A stent according to claim 14 wherein the domed segment further comprises an axially extending protuberance adapted for facilitating insertion of the stent into a patient.

16. A stent according to claim 15 wherein the axially extending protuberance has a through aperture sized to accommodate a guide wire.

17. A stent according to claim 1 wherein the wall of the stent includes a radio-opaque material.

18. A stent according to claim 1 wherein the wall comprises a coating.

19. A delivery system for deploying a self-expanding stent within a body lumen comprising:

a retractable sheath comprising a wall and a proximal portion and a distal portion, the retractable sheath defining an internal lumen extending from the proximal portion to the distal portion, the internal lumen for containing the stent in a collapsed state at the distal portion of the sheath, the wall defining a first groove and a longitudinal opening through the proximal portion of the sheath, the first groove connected to and lying perpendicular to a proximal end of the longitudinal opening;

a shaft partially disposed and slidably movable within the lumen of the sheath, the shaft comprising at least one second groove; and

a rotatable locking element disposed over the proximal portion of the sheath, the locking element comprising a tongue adapted to engage the first groove of the sheath and the at least one second groove of the shaft, the stent being delivered by rotating the locking element to position the tongue in the longitudinal opening of the sheath, and then retracting the sheath over the shaft.

20. The delivery system of claim 19 further comprising a retraction handle disposed on the proximal portion of the sheath, the retraction handle adapted to retract the sheath over the shaft.

21. The delivery system of claim 19 further comprising an insertion handle disposed on a distal end of the shaft, the insertion handle adapted to insert the delivery system into a body of a patient.

22. The delivery system of claim 19 wherein the sheath comprises at least one radiopaque locator band.

23. The delivery system of claim 19 wherein the shaft comprises a plurality of second grooves.

24. The delivery system of claim 19 further comprising a slidable stop cup disposed about the sheath to position the delivery system against a body of a patient before deploying the stent.

25. The delivery system of claim 19 wherein the locking element further comprises a thumb tab.

26. The delivery system of claim 19 wherein a distal end of the distal portion of the sheath is rounded.

27. The delivery system of claim 19 wherein a distal end of the distal portion of the sheath comprises a plurality of longitudinal slits.

28. The delivery system of claim 19 wherein a distal end of the shaft expands radially to abut the stent.

29. The delivery system of claim 19 further comprising a collapsible and expandable stent disposed within the sheath.

30. A method of placing a stent, the method comprising,

providing a stent having,

a wall, disposed between the first and second terminal ends, and including an inner surface and an outer surface, the inner surface defining a lumen extending between the first and second ends, and the outer surface having a substantially smooth portion, the wall having,

a first outside cross-sectional diameter at the first terminal end, a second outside cross-sectional diameter at the second terminal end, and at least one intermediate outside cross-sectional diameter at an intermediate location between the first and second terminal ends, wherein at least one of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter, and

an expanded state and a collapsed state, the wall being adapted to spontaneously revert from the collapsed state to the expanded state.

31. The method of claim 30 wherein the step of inserting comprises,

positioning the first terminal end of the stent at the bladder end of the prostatic urethra.

32. The method of claim 30 wherein the step of inserting comprises,

positioning the second terminal end of the stent at the external sphincter end of the prostatic urethra.

33. The method of claim 30 wherein the step of providing the stent comprises,

providing the stent in the collapsed state.

34. A method of making a stent, the method comprising,

providing an injection mold that profiles the stent,

injecting liquid polymer into the injection mold,

allowing the liquid polymer to cure, and

removing the cured polymer for the injection mode, the cured polymer forming a stent having,

a wall, disposed between the first and second terminal ends, and including an inner surface and an outer surface, the inner surface defining a lumen extending between the first and second ends, and the outer surface having a substantially smooth portion, the wall having,

a first outside cross-sectional diameter at the first terminal end, a second outside cross-sectional diameter at the second terminal end, and at least one intermediate outside cross-sectional diameter at an intermediate location between the first and second terminal ends, wherein at least one of the first and second outside cross-sectional diameters is greater than the intermediate outside cross sectional diameter, and

an expanded state and a collapsed state, the wall being adapted to spontaneously revert from the collapsed state to the expanded state.

35. A method of placing a collapsible and expandable stent within a body of a patient, comprising:

providing a collapsible and expandable stent and a delivery system, the delivery system comprising

a retractable sheath including a proximal portion and a distal portion, the sheath defining an internal lumen extending from the proximal portion to the distal portion, the internal lumen for containing the stent in a collapsed state at the distal portion of the sheath, the wall defining a first groove and a longitudinal opening through the proximal portion of the sheath, the first groove connected to and lying perpendicular to a proximal end of the longitudinal opening;

a shaft partially disposed and slidably movable within the lumen of the sheath, the shaft comprising at least one second groove; and

a rotatable locking element disposed over the proximal portion of the sheath, the locking element comprising a tongue adapted to engage the sheath into the at least one groove of the shaft;

inserting the delivery system with the stent collapsed within the sheath into the body of the patient;

retracting the sheath over the shaft; and

removing the delivery system from the body of the patient, thereby deploying the stent within the body.

36. The method of claim 35 wherein the delivery system further comprises a slidable stop cup disposed about the shaft and a thumb tab disposed on the locking element, and further comprising the step of locking the slidable stop cup against a head of a penis of the patient before insertion of the delivery system.

37. The method of claim 35 further comprising inserting the stent, in its collapsed state, into the sheath before the inserting step.

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